Gen4 Instrument Refurbishment Pilot

Results and Lessons Learned

September 2020

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Quick History

- **Project Dragon** (2017-2018)
  - Determine if a lower priced instrument offering through reclamation and refurbishment of ISI Core instruments increases procedure volume in cost sensitive regions
- **Refurbishment Pilot** (2019-2020)
  - Collect instruments to test refurbishment process in Sunnyvale on a small scale
  - Develop potential business models (reviewed in 2019 and handed off to IA&E Marketing)
- **Reclamation v. Refurbishment v. Remanufacturing**
  - Reclamation: Collection of expired instruments for disposal and/or refurbishment
  - Refurbishment: Restores a medical device to the OEM's original specifications or to be "like new." The device may be brought to current specifications if the change(s) made to the device do not significantly change the finished device's performance or safety specifications, or intended use.
  - Remanufacturing: Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance or safety specifications, or intended use

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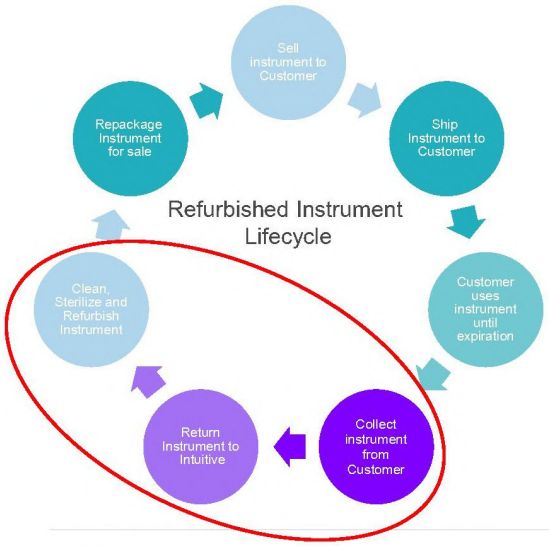
Scope of the Pilot



- US only pilot to collect top 6 Xi reusable instruments utilizing an external partner (Stericycle)
  - Monopolar Curved Scissors
  - Maryland Bipolar Forceps
  - Fenestrated Bipolar Forceps
  - Large Needle Driver
  - Prograsp
  - Mega Suturecut Needle Driver
- Test of reclamation and refurbishment process with results feeding financial analysis
- Functional Teams involved:
  - Logistics, Facilities, I&A Manufacturing, I&A New Product Verification, RMA, Svc Mktg

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Pilot Goals

1) Understand collections logistic
2) Understand customer compliance/collection yield
3) Confirm refurbishment yield assumptions
4) Understand financial aspects associated with collection and Refurbishment

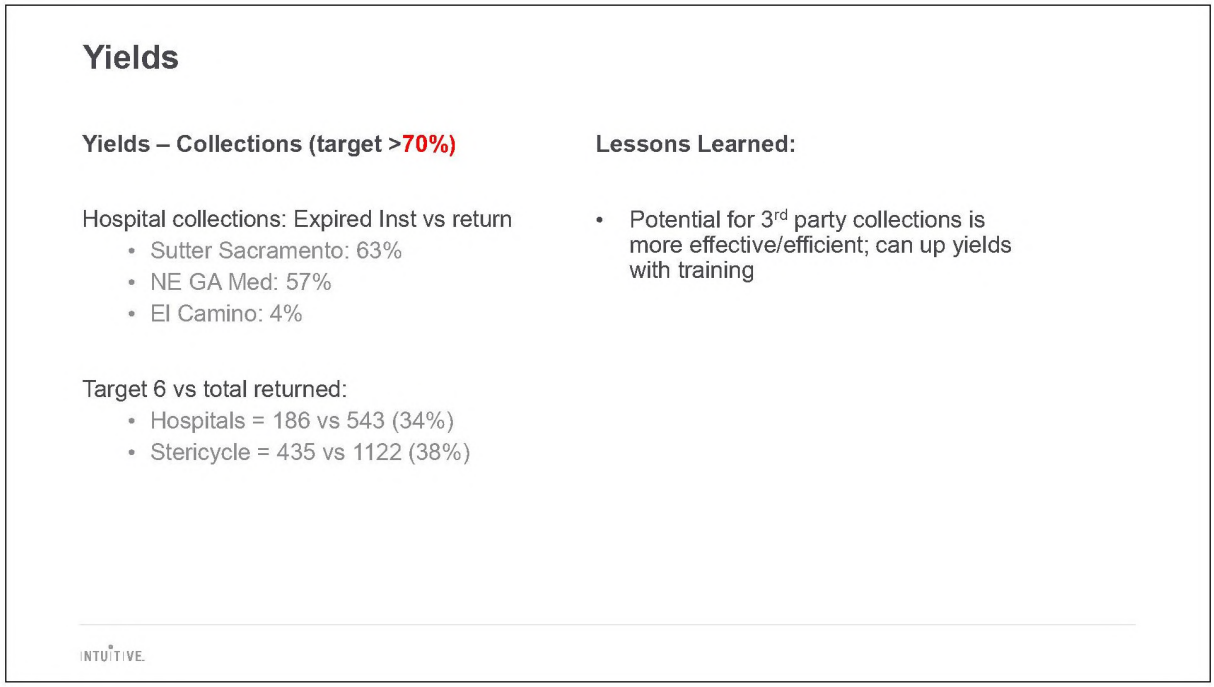
Reclamation

Partnership with Stericycle

- **Why work with an external partner?**
  - Time savings
  - Reduce variables
- **Scope of Work**
  - Identify appropriate sized bins and labeled for Intuitive
  - Share customer list allowing Intuitive to target appropriate customers
  - Place bins in hospital where requested by customer (OR, SPD, etc.)
  - Train customers on what to place in the bins
  - Collect bins from customers and ship to Intuitive
- **Costs**
  - $95/bin collected, collection of minimum 2 bins at a time
  - $150/12 bins to ship back to Stericycle
- **Other company considered**
  - Medline Renewal was original target company based on project Dragon
- **Lessons learned**
  - No single collection company will cover all Intuitive customers
  - Several of the market share leaders in collection are potentially adversarial to Intuitive due to 3rd party resale and remanufacturing (Stryker, Medline in US, others OUS)
  - Companies like Stericycle could offer additional services such as sorting at their facilities or ability to bypass interaction with customers (don't necessarily need an Intuitive specific bin)

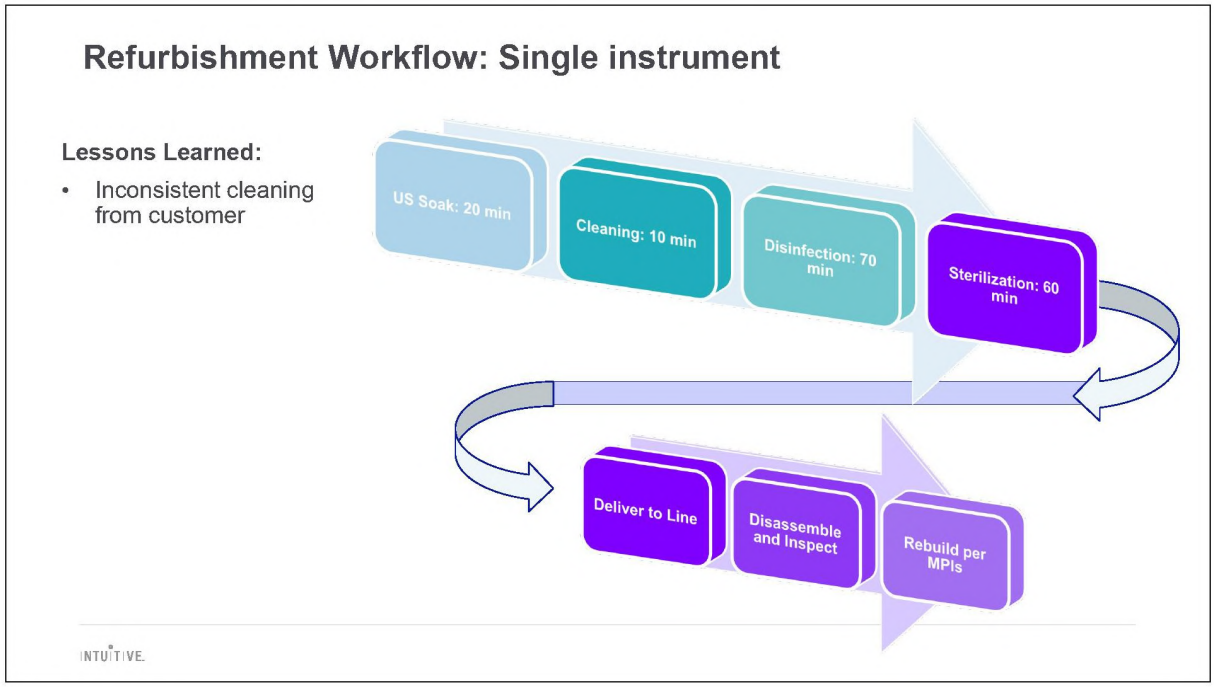
Customer Engagement and Compliance

- **Enrolling hospitals**
  - 17 high volume sites approached to potentially participate
  - 3 sites actually participated to differing levels of compliance (2 additional sites signed NDA's but refused to go beyond that point)
  - For pilot, no financial incentives were given. Those that participated appreciated the idea of being more green
- **Customer compliance**
  - For simplicity, asked customers to place any Xi reusable expired instrument in bin
  - Volume of expired instruments identified from logs did not match what was received
- **Bins from Stericycle facility**
  - Due to lack of volume from customers, also received bins from Stericycle sorting facility.
  - We requested just top 6 instruments from Stericycle but received more. Stericycle felt with training the goal of just the 6 could be met in the future.
- **Lessons learned**
  - Needed to engage elements at customer sites we don't normally deal with (procurement, contracting, waste management)
  - Customers often have specific contracts with reclamation companies/waste companies that are challenging to work around
  - Bin fatigue as often there already are 4+ bins in/around OR



Data is as compared to hospital log information

Refurbishment



Major parts scrapped: RFID, Grip & Pitch cables, clamping pulley, hypotube, cover, conductor wire, inputs, flush tube , EOL Flag
Parts retained: main tube, roll input, roll gear, chassis, idler pulley, clevis, grips (non cautery)

Testing Strategy

- **Three Tier Plan:**
  - Tier 1: Prove 10 lives with Standard recipe
  - Tier 2: Test to failure with Standard recipe
  - Tier 3: Test to failure with Ad-Hoc recipe

- **Results:**
  - Tier 1: Demonstrated 10 life compatibility for LND, Prograsp, MSCND, MBP. FBF in process. MCS not proven
  - Tier 2: TBD
  - Tier 3: Remove from scope

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FBF currently on SSU 12 of 19
MCS failure due to cable breaks cause by a seized distal pully

Refurbishment Process

- **Standard instrument line**, minimal equipment
  - 1 HIPT
  - No marking

- **Lessons learned:**
  - Build instructions require additional SME training to successfully refurbish first instruments
  - Additional inspection of distal pulleys should be performed if retained as part of refurbishment

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Refurbishment Results: N=10 Lives

Yields – Refurbishment (target >70%)

LND: 84% (42 inst)
MCS: 81% (48 Inst)
MSCND: 95% (41 inst)
Maryland: 88% (44 inst)
FBF: 67*% (50 inst)
Prograsp: 96% (50 inst)
Average: 85%

*High scrap (~10) due to soiling.

Scrap Costs (target < 50%)

** Projected with process improvements

Refurb costs by instrument type	Scrapped Parts	% of Original BOM cost:
BPM	$90.65	55%
FBF	$82.59	56%
MCS	$150.87	68%
MSCND	$62.49	30%
Prograsp	$59.10	45%
LND	$51.26	37%

Refurb costs by instrument type	Scrapped Parts	% of Original BOM cost:
BPM**	$63.50	39%
FBF**	$56.30	38%
MCS**	$150.87	68%
MSCND	$62.49	30%
Prograsp	$59.10	45%
LND	$51.26	37%

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Financial Results

Reclamation and Refurbishment Costs (SV Pilot)

Per Instrument (Current State)	Monopolar Curved Scissors (MCS)	Maryland Bipolar Forceps	Fenestrated Bipolar Forceps (FBF)	Large Needle Driver (LND)	Prograsp	Mega Suturecut Needle Drive (MSCND)
New Build COGS	$206	$156	$141	$136	$128	$197
Collection Rate	40%	40%	40%	40%	40%	40%
Refurbishment Yield	81%	88%	70%	84%	95%	95%
Bin Collection/Handling (Stericycle)	$5.51	$5.51	$5.51	$5.51	$5.51	$5.51
Bag & Box for Bin	$0.72	$0.72	$0.72	$0.72	$0.72	$0.72
Shipping	$1.50	$1.50	$1.50	$1.50	$1.50	$1.50
Sort/Visual/Brush&Flush	$5.00	$5.00	$5.00	$5.00	$5.00	$5.00
Washer/Disinfector Consumables	$2.06	$2.06	$2.06	$2.06	$2.06	$2.06
Disposal in SH	$0.40	$0.40	$0.40	$0.40	$0.40	$0.40
Total Variable Reclamation Cost	**$15.19**	**$15.19**	**$15.19**	**$15.19**	**$15.19**	**$15.19**
Disassembly Cost SNV ($)	16.50	16.50	16.50	16.50	16.50	16.50
Value Harvested per Instrument	$63	$84	$62	$86	$70	$138
Mfg Labor per Instrument (SNV)	$83.2	$83.2	$83.2	$83.2	$83.2	$83.2
Materials needed for Remanufacture	$141	$71	$77	$48	$55	$57
Total Variable Cost of Remufacture	$224.02	$154.01	$160.24	$131.07	$138.30	$139.71
Total COGS Refurb (Inc. Disposal)	$263.14	$190.02	$205.51	$168.79	$171.66	$173.06
% Reclamation Cost	7.1%	9.1%	10.6%	10.7%	9.3%	9.2%
% Disassembly	7.7%	9.9%	11.5%	11.6%	10.1%	10.0%
Savings vs New Build	-$57.45	-$33.63	-$64.97	-$32.42	-$43.75	$23.76

*Return Incentive not included in the above calculations

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Reclamation and Refurbishment Costs (Future State – 100% SH)

Per Instrument (100% SH Build)	Monopolar Curved Scissors (MCS)	Maryland Bipolar Forceps	Fenestrated Bipolar Forceps (FBF)	Large Needle Driver (LND)	Prograsp	Mega Suturecut Needle Drive (MSCND)
New Build COGS	$206	$156	$141	$136	$128	$197
Collection Rate	40%	40%	40%	40%	40%	40%
Refurbishment Yield	90%	90%	90%	85%	95%	95%
Bin Collection/Handling (Stericycle)	$5.51	$5.51	$5.51	$5.51	$5.51	$5.51
Bag & Box for Bin	$0.72	$0.72	$0.72	$0.72	$0.72	$0.72
Shipping	$1.50	$1.50	$1.50	$1.50	$1.50	$1.50
Sort/Visual/Brush&Flush	$5.00	$5.00	$5.00	$5.00	$5.00	$5.00
Washer/Disinfector Consumables	$2.06	$2.06	$2.06	$2.06	$2.06	$2.06
Disposal in SH	$0.40	$0.40	$0.40	$0.40	$0.40	$0.40
Total Variable Reclamation Cost	**$15.19**	**$15.19**	**$15.19**	**$15.19**	**$15.19**	**$15.19**
Disassembly Cost SH($)	6.50	6.50	6.50	6.50	6.50	6.50
Value Harvested per Instrument	$63	$84	$62	$86	$70	$138
Mfg Labor per Instrument (SH)	$33.8	$33.8	$33.8	$33.8	$33.8	$33.8
Materials needed for Remanufacture	$141	$71	$77	$48	$55	$57
Total Variable Cost of Remufacture	$174.62	$104.61	$110.84	$81.67	$88.90	$90.31
Total COGS Refurb (Inc. Disposal)	$198.72	$128.71	$134.94	$107.18	$111.73	$113.14
% Reclamation Cost	8.5%	13.1%	12.5%	16.7%	14.3%	14.1%
% Disassembly	3.6%	5.6%	5.4%	7.1%	6.1%	6.0%
Savings vs New Build	$6.97	$27.69	$5.60	$29.19	$16.18	$83.68

*Return Incentive not included in the above calculations
SH Cost assumed at $39/hr

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Reclamation and Refurbishment Costs (Future State – 100% MX)

Per Instrument (100% MX Build)	Monopolar Curved Scissors (MCS)	Maryland Bipolar Forceps	Fenestrated Bipolar Forceps (FBF)	Large Needle Driver (LND)	Prograsp	Mega Suturecut Needle Drive (MSCND)
New Build COGS	$206	$156	$141	$136	$128	$197
Collection Rate	40%	40%	40%	40%	40%	40%
Refurbishment Yield	90%	90%	90%	85%	95%	95%
Bin Collection/Handling (Stericycle)	$5.51	$5.51	$5.51	$5.51	$5.51	$5.51
Bag & Box for Bin	$0.72	$0.72	$0.72	$0.72	$0.72	$0.72
Shipping	$1.50	$1.50	$1.50	$1.50	$1.50	$1.50
Sort/Visual/Brush&Flush	$5.00	$5.00	$5.00	$5.00	$5.00	$5.00
Washer/Disinfector Consumables	$2.06	$2.06	$2.06	$2.06	$2.06	$2.06
Disposal in SH	$0.40	$0.40	$0.40	$0.40	$0.40	$0.40
Total Variable Reclamation Cost	**$15.19**	**$15.19**	**$15.19**	**$15.19**	**$15.19**	**$15.19**
Disassembly Cost MX($)	1.83	1.83	1.83	1.83	1.83	1.83
Value Harvested per Instrument	$63	$84	$62	$86	$70	$138
Mfg Labor per Instrument (MX)	$9.5	$9.5	$9.5	$9.5	$9.5	$9.5
Materials needed for Remanufacture	$141	$71	$77	$48	$55	$57
Total Variable Cost of Remufacture	$150.35	$80.34	$86.57	$57.40	$64.63	$66.04
Total COGS Refurb (Inc. Disposal)	$169.26	$99.25	$105.48	$77.43	$82.55	$83.96
% Reclamation Cost	10.0%	17.0%	16.0%	23.1%	19.4%	19.0%
% Disassembly	1.2%	2.1%	1.9%	2.8%	2.3%	2.3%
Savings vs New Build	$36.42	$57.14	$35.05	$58.94	$45.36	$112.86

*Return Incentive not included in the above calculations
MX cost assumed at $11/hr

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Wrap up

Next Steps

- **Three Tier Plan:**
  - Tier 2: Test to failure with Standard recipe
- **Define scalability requirements**
- **Timeline:** 6 months
- **Resources:**
  - 0.10 PM
  - 0.10 TE
  - 2 techs
  - $60K expenses
- **Handoff:**
  - Once all above steps are complete, fully handoff to IA&E BU to determine any future of reclamation and/or refurbishment

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Q&A